

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

<i>In re</i> Patent Application of:	)
<b>R. Sam NIEDBALA <i>et al.</i></b>	) Art Unit: 1743
Serial No.: <b>09/997,023</b>	) Examiner: Lyle A. Alexander
Filed: <b>November 30, 2001</b>	) Confirmation No: 6134
For: <b>SAMPLE COLLECTOR AND TEST</b>	)
<b>DEVICE</b>	)

Mail Stop **AMENDMENT**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY UNDER 37 C.F.R. § 1.111**

Sir:

In response to the Office Action mailed October 2, 2007, please amend the above-identified application and consider Applicants' remarks as follows.

**The Claims** are reflected in the listing of claims which begin on page 2 of this paper.

**Remarks** begin on page 9 of this paper.

The listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1. (Previously Presented) A sample collection device for assay comprising:  
a holding portion having a holding portion first end and a holding portion second end;  
a retaining portion having a retaining portion first end operably connected to a retaining portion second end, the retaining portion first end being coupled to the holding portion second end and the retaining portion second end being movable relative to the holding portion second end, the retaining portion having at least an extended size and a contracted size, the sizes being defined by a configurable distance between the retaining portion second end and the holding portion first end; and  
an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size;  
wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size; and  
wherein the retaining portion includes a discharge member at the retaining portion second end spaced from the holding portion second end, the collector member being disposed between the discharge member and the holding portion second end, wherein when the retaining portion second end is moved relative to the holding portion second end to reconfigure the retaining portion from the extended size to the contracted size, a sample portion sufficient for assay is discharged from the discharge member.
2. (Original) The sample collection device for assay of claim 1, wherein the retaining portion includes a blocking portion defining a sample retaining size of the retaining portion and preventing movement of the retaining portion to a size that is less than the sample retaining size, the sample retaining size being formed when the blocking portion engages with the holding portion second end.
3. (Canceled)
4. (Previously presented) The sample collection device for assay of claim 1, wherein the collector member is made from a fluid absorbing material and the sample is discharged from the collector member by squeezing the collector member between the discharge member and the holding portion second end.

5. (Canceled)

6. (Original) The sample collection device for assay of claim 2, wherein the retaining portion includes an elongate member, the blocking portion includes a raised portion formed on the elongate member, and the holding portion second end includes a wall sized to engage with the raised portion when the retaining portion is moved from one of the extended size and the contracted size to the sample retaining size.

7. (Previously presented) The sample collection device for assay of claim 1, wherein the holding portion includes a housing defining an opening for slidably receiving the retaining portion so as to permit the retaining portion to be selectively movable between at least one of an extended size and a contracted size.

8. (Canceled)

9. (Previously presented) The sample collection device for assay of claim 1, wherein the expandable collector member is made from a fluid absorbing material and the sample portion is discharged from the discharge member by squeezing the collector member between the discharge member and the holding portion second end.

10-11. (Canceled)

12. (Previously presented) The sample collector device for assay of claim 1, wherein the collector member has a first length when the collector member has a first collection size, the collector member has a second length when the collector member has a second collection size, and the retaining portion describes an extended length when the retaining portion has a extended size, wherein a sufficient sample is collected for assay when the second length is substantially equal to the extended length.

13. (Previously presented) The sample collector device for assay of claim 1, wherein the collector member size is reduced from a second collection size to a first collection size when the retaining portion is configured from the extended size to the contracted size.

14. (Original) A test device in combination with the sample collector device for assay of claim 1, the test device being adapted to connect with the sample collection device and including a tester to assay for analytes in the sample, the test device including

an opening sized to receive the holding portion,

a discharge surface adapted to engage with the retaining portion, wherein the collector member second collection size is substantially equal to the retaining portion extended size before engaging the retaining portion with the discharge surface, and the sample collector is in fluid

communication with the tester and the retaining portion is configured in the contracted size when the retaining portion is engaged with the discharge surface.

15. (Original) The test device in combination with the sample collector device for assay of claim 14, wherein the holding portion second end includes an engagement surface and the test device includes a mating surface adapted to engage with the engagement surface, wherein the holding portion is fixed to the test device when the engagement surface engages with the mating surface.

16. (Original) The test device in combination with the sample collector device for assay of claim 15, wherein the mating surface engages with the engagement surface by elastic deformation of at least one of the mating surface and the engagement surface.

17. (Original) The test device in combination with the sample collector device for assay of claim 15, wherein the holding portion is fixed to the test device by a friction fit between the engagement and mating surfaces.

18. (Original) The test device in combination with the sample collector device for assay of claim 15, wherein the collector member second collection size is substantially equal to the retaining portion extended size when the mating surface engages with the engagement surface.

19. (Original) The test device in combination with the sample collector device for assay of claim 15, wherein the holding portion includes a second engagement surface and the test device includes a second mating surface adapted to engage with the second engagement surface, wherein when the second engagement surface is in contact with the second mating surface, the discharge surface engages with the retaining portion.

20. (Original) The test device in combination with the sample collector device for assay of claim 14, wherein the tester is a lateral flowstrip in fluid communication with the collector member when the holding portion is fixed to the test device and the retaining portion is in the contracted size.

21. (Original) The test device in combination with the sample collector device for assay of claim 14, wherein the test device further includes an ampoule containing fluid and the ampoule is violated when the collector member is equal to the first collection size.

22. (Original) The test device in combination with the sample collector device for assay of claim 14, wherein the holding portion first end comprises a handle and the first end is removable from the second end.

23. (Original) The sample collection device for assay of claim 1, wherein the second

amount of sample corresponds to an assay sample that is substantially contained in the collector member, the assay sample being transferable from the collector member to a test device for assay of the assay sample.

24. (Canceled)

25. (Original) The test device in combination with the sample collector device for assay of claim 14, wherein the collector member has the first collection size when the sample collector is in fluid communication with the tester.

26-45. (Canceled)

46. (Previously Presented) A sample collection device for assay comprising:  
a holding portion having a first end and a second end;  
a retaining portion having a retaining portion first end operably connected to a retaining portion second end, the retaining portion first end being coupled to the holding portion second end and the retaining portion second end being movable relative to the holding portion second end, the retaining portion having at least an extended size and a sample retaining size, the sample retaining size being smaller than the extended size, the sizes being defined by a configurable distance between the retaining portion second end and the holding portion second end;

a blocking portion disposed on the retaining portion, the blocking portion being spaced from the holding portion second end when the retaining portion is configured in the extended size and the blocking portion being engaged with the holding portion second end when the retaining portion is configured in the sample retaining size, and

an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of sample and a second collection size when the collector member has a second amount of sample;

wherein the collector member has the second collection size when the blocking member is spaced from the holding portion second end and the collector member has the first collection size when the blocking member is engaged with the holding portion second end,

wherein the first amount of sample is sufficient for a first assay of sample and the second amount of sample is sufficient for a second assay of the sample.

47. (Original) The sample collection device for assay of claim 46, wherein the blocking portion is formed on the retaining portion.

48. (Original) The sample collection device for assay of claim 47, wherein the retaining portion includes a first part including the blocking portion and a second part that is smaller than the

first part and wherein the second part is received within the holding portion when the retaining portion is configured from the extended size to the sample retaining size.

49. (Original) The sample collection device for assay of claim 46, the retaining portion further comprising

a first elongate portion having a first length and a first width dimension wherein the first length substantially corresponds to the sample retaining size, and

a second elongate portion having a second width dimension,

wherein the holding portion second end defines an opening sized for slidably receiving the retaining portion, the opening defining a width dimension that is smaller than the first width and greater than the second width.

50. (Original) The sample collection device for assay of claim 49, wherein the retaining portion is a cylinder and the first width corresponds to a first diameter of the cylinder and the second width corresponds to a second diameter of the cylinder.

51. (Original) The sample collection device for assay of claim 46, wherein when the collector member has a first collection size and the retaining portion is configured from the extended size to the sample retaining size, the collector member is configured from the second collection size to the first collection size and a sample sufficient for the first assay is expressed from the collector member.

52. (Original) The sample collector device for assay of claim 46, wherein the collector member is made from a fluid absorbing material and the retaining portion expresses fluid sufficient for assay of sample from the collector member when the retaining portion is configured from the extended size to the sample retaining size.

53-72. (Canceled)

73. (Previously Presented) A sample collection device for assay comprising:

a holding portion having a first end and a second end;

a retaining portion having a retaining portion first end operably connected to a retaining portion second end, the retaining portion first end being coupled to the holding portion second end and the retaining portion second end being movable relative to the holding portion second end, the retaining portion having at least an extended size and a contracted size, the sizes being defined by a configurable distance between the retaining portion second end and the holding portion second end; and

an expandable collector member disposed on the retaining portion and having a first

collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size;

wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size, and wherein the retaining portion includes a discharge member at the retaining portion second end spaced from the holding portion second end, the collector member being disposed between the discharge member and the holding portion second end, wherein when the retaining portion second end is moved relative to the holding portion second end to reconfigure the retaining portion from the extended size to the contracted size, a portion of the sample in the retaining portion suitable for assay is discharged from the collector member.

74. (Previously presented) The sample collection device for assay of claim 75, wherein the second amount of sample includes a first assay sample and a second assay sample.

75. (Previously presented) The sample collection device for assay of claim 73, wherein the collector member is made from a fluid absorbing material and the sample is discharged from the collector member by squeezing the collector member between the discharge member and the holding portion second end.

76. (Previously presented) The sample collection device for assay of claim 74, wherein the collector member contains a third amount of sample when the collector member size is substantially equal to the sample retaining size, and wherein the second amount of sample is usable for a primary assay and the third amount of sample is usable for a secondary assay.

77. (Previously Presented) A sample collection device for assay comprising:

a holding portion having a first end and a second end;

a retaining portion coupled to the holding portion second end and selectively configurable between at least an extended size and a contracted size; and

an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size;

wherein a sufficient sample is collected for assay when the collector member second collection size is substantially equal to the retaining portion extended size, wherein the retaining portion includes a wall spaced at a first length from the holding portion second

end when the retaining portion is in the expanded size and the wall is spaced at a second length from the holding portion second end when the retaining portion is in the contracted size,

wherein the retaining portion is an elongate member having a proximal end adjacent the holding portion second end and a perforated disc-like piece formed at a distal end, the perforated disc-like piece comprising the wall, and

wherein the collector member is made from a fluid absorbing material that is movable along the elongate member when the collector member has the first collection size.

78. (Canceled)



### REMARKS

The Office Action mailed March 28, 2007 has been received and carefully considered. Claims 1, 2, 4, 6, 7, 9, 12-23, 25, 46-52, and 73-77 are now pending in the application. Claims 3, 5, 8, 10-11, 24, 26-45, 53-72, and 78 have been canceled. No new matter has been added.

#### ***Rejections under 35 U.S.C. § 102***

On page 2 of the Office Action, the Examiner rejects claims 1, 2, 4, 6, 7, 9, 12-23, 25, 46-52, and 73-77 under 35 U.S.C. § 102(b) “as being anticipated by U.S. Pat. No. 4,014,322 to Shah.” More specifically, the Examiner argues that the device disclosed in Shah, “comprising a chamber (28), a lid (34) having aperture (38), elongated shaft (40) absorbent/sponge (56) attached to shaft (4) and plate (5) attached to bottom of the shaft (4) below the absorbent/sponge (56)” reads on an element of claim 1 of the present invention reciting “a retaining portion having a retaining portion first end operably connected to a retaining portion second end, the retaining portion first end being coupled to the holding portion second end and the retaining portion second end being movable relative to the holding portion second end, the retaining portion having at least an extended size and a contracted size, the sizes defined by a distance between the retaining portion second and the holding portion first end.” *Id.* at 3-4. Applicants respectfully traverse this rejection.

Anticipation under 35 U.S.C. § 102 requires that a single prior art reference disclose *each and every limitation* of the claimed invention. *Electro Med. Sys. S.A. v. Cooper Life Sci.*, 34 F.3d 1048, 1052, 32 USPQ2d 1017, 1019 (Fed. Cir. 1994) (emphasis added). “[F]or anticipation under 35 U.S.C. 102, the reference must teach *every aspect* of the claimed invention either explicitly or impliedly.” MPEP 706.02(IV) (emphasis added).

The device referred to by Shah is potentially relevant to perhaps one aspect of the claimed invention to which the Examiner refers while ignoring the rest of the claim limitations. For example, Shah patent does not refer to “an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size,” as recited in claim 1. Thus, because Shah does not teach each and every limitation of the claimed invention, Shah does not support a § 102 rejection, and applicants respectfully request that the rejection be withdrawn.

***Rejections under 35 U.S.C. § 103***

On page 3 of the Office Action, the Examiner rejects claim 77 under 35 U.S.C. § 103(a) “as being unpatentable over Shah”. Applicants traverse the rejection.

The Examiner concedes that “Shah is silent to the claimed ‘perforated disk-like piece formed at a distal end,’” yet asserts that this element of the invention is obvious, citing *In re Boesch*, 617 F.2d 272 (C.C.P.A. 1980), as legal support for this assertion. The Examiner argues that because Boesch held that “optimization of a result effective variable is ordinarily within the skill of the art” therefore “[t]he choice of making a piece for expressing fluid from a solid piece or a perforated piece would have the well known and predictable results of facilitating the expression of the fluid.”

The point raised by the Examiner concerning “optimization of a result effect variable” is of no significance in the present case. *In re Boesch* and the similar cases cited, for example, in the MPEP 2144.05 refer to the obviousness of ranges and are inapplicable to the instant claims. The Board of Patent Appeals and Interferences instructed, in a non-precedential opinion, that:

Admittedly, there are cases which have held that “optimization” may not in itself patentably distinguish the claimed subject matter over the prior art. However, in all of the authorities known to us, the optimization relates to a range or a variable. See, for example, *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) (The discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art and, hence, obvious.)... [I]n the present case, patentability of appellant’s claimed invention is predicated on a difference in structure, and not on a change in a variable. The rule in Boesch therefore is not applicable to the present case, especially in view of the fact that the examiner has not cited any authority for extending the *Boesch* principle concerning changes in a variable to a situation in which an apparatus has been structurally modified to achieve a certain result.

*In re Barth*, Appeal No. 1998-0982, Application No. 08/399,715 (1999).

Even if Shah had some relevance to the disc-like piece, Shah in no way renders obvious the limitation of claim 77 reciting “an expandable collector member disposed on the retaining portion and having a first collection size when the collector member has a first amount of the sample and a second collection size when the collector member has a second amount of the sample, the first collection size being less than the second collection size.” Shah merely refers to “a device for collecting a urine specimen in a simplified and aseptic manner,” page 1, lines 41-42, “comprising a chamber (28), a lid (34) having aperture (38), elongated shaft (40) absorbent/sponge (56) attached to shaft (4) and plate (5) attached to bottom of the shaft (4) below the absorbent/sponge (56),” as described by the Examiner. There is nothing in Shah to suggest a device that includes the claimed sample retaining feature.

Hence, Shah does not support a § 103 rejection, and Applicants respectfully request that the rejection of claim 77 be withdrawn.

The Applicants acknowledge the Examiner's discussion of art on page 4 of the Office Action.

***Conclusion***

In view of the foregoing, the present application is now believed to be in condition for allowance. Should the Examiner find some issue to remain unresolved, however, or should any new issues arise that could be resolved through discussions with Applicants' representative, then the Examiner is invited to telephone the undersigned to expedite further prosecution of this application.

**Except** for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. § 1.16 and § 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. §1.136(a)(3).

Respectfully submitted,

Date: February 20, 2008

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